

REMARKS

Claims 40-48 are presented.

Claim 40 has been amended, thereby addressing the rejection under 35 U.S.C. § 112, second paragraph. Applicants regret any confusion caused by their prior amendment.

The only remaining issue is the rejection of claims 40-48 under 35 U.S.C. § 112, first paragraph. The Examiner alleges that the claims are not enabled. The rejection is traversed.

The Examiner agrees that applicants exemplify that “reducing NS3 residues dramatically improves the ability of the NS3 antigen to bind antibodies.” In other words, example 5 demonstrates proof of what is claimed. The Examiner argues, however, that because applicants have shown that antigenicity is strongly determined by the cysteine residues, “any modification to the cysteine residues has the potential to destroy the immunological activity of the NS3 polypeptide.”

This, however, is speculation, unsupported by evidence, and in fact contradicted by the evidence of record. Where is the Examiner’s proof that the exemplification is not support for what is claimed? There is none.

In re Marzocchi, 439 F.2d 220, 223-224, 169 USPQ 367, 369-370 (CCPA 1971), provides clear instructions as to what the Examiner must provide when enablement is doubted.

As a matter of Patent Office practice...a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statement contained therein which must be relied on for enabling support ...

...Most often, additional factors, such as the teachings in pertinent references, will be available to substantiate any doubts that the asserted scope of objective enablement is in fact commensurate with the scope of protection sought and to support any demands based thereon for proof... {I}t is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.”

Further, In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991), quoting In re Wands which was relied upon by the Examiner, states:

...the specification [must]...enable any person skilled in the art to which it pertains to make and use the claimed invention. Although the statute does not say so, enablement requires that the specification teach those in the art to make and use the invention without “undue experimentation.” In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). That some experimentation may be required is not fatal; the issue is whether the amount of experimentation required is “undue.” Id. At 736-37, 8 USPQ2d at 1404.

Indeed, even In re Wands, 858 F.2d 731, 737, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988), states:

“Enablement is not precluded by the necessity for some experimentation such as routine screening.”

Also see Ex parte Jackson, 217 USPQ 804, 807 (Bd. Appl. 1982):

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.

Finally, as stated by In re Angstadt, 537 F.2d 498, 503-04, 190 USPQ 214, 218-219 (CCPA 1976):

If...the disclosure must provide “guidance which will enable one skilled in the art to determine, with reasonable certainty

before performing the reaction, whether the claimed product will be obtained” (emphasis in original), as the dissent claims, then all “experimentation” is “undue,” since claims the term “experimentation” implies that the success of the particular activity is uncertain. Such a proposition is contrary to the basic policy of the Patent Act, which is to encourage disclosure of inventions and thereby to promote progress in the useful arts. To require disclosures in patent applications to transcend the level of knowledge of those skilled in the art would stifle the disclosure of inventions in fields man understands imperfectly, like catalytic chemistry. The Supreme Court said it aptly in Minerals Separation, Ltd. vs. Hyde, 242 U.S. 261, 270-271 (1916)...:

...the certainty which the law requires in patents is not greater than is reasonable, having regard to their subject matter...

The specification teaches the HCV NS3 region, together with the cysteine residues that are a part of it. It teaches various methods for reducing those residues. It is conceivable that not all of the possibilities will work; however, they do not have to. The case law does not require that every embodiment covered by a claim actually function. It is the burden of the Examiner to show why it is more likely than not that a claimed invention will not function, and to satisfy the standards set forth by the case law cited supra. It is submitted that the Examiner has not come close to satisfying this standard. Rather, the Examiner’s position seems to be that, since one modification worked, it is likely that others will not. Again, where is the evidence for this?

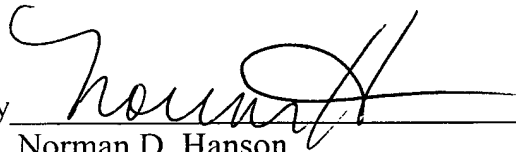
Previously, in the grandparent case, applicants showed that other modifications were successful. They bring the Examiner’s attention to the declaration filed in that case, i.e., Serial No. 08/892,704, and append a copy.

The combination of these materials and the Examiner’s failure to carry the burden of overcoming the presumption of enablement must lead to withdrawal of the rejection and allowance of the application.

A TELEPHONE INTERVIEW WITH THE EXAMINER AND SPE SHOULD
THIS CASE NOT BE ALLOWED IS REQUESTED.

Respectfully submitted,

FULBRIGHT & JAWORSKI L.L.P.

By 
Norman D. Hanson
Reg. No. 30,946

666 Fifth Avenue
New York, NY 10103
212-318-3168
212-318-3400 (fax)

Enclosure: Declaration